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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/074,389 | 02/12/2002 | Mark A. Scialdone | CL1723 US NA | 5572 |

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EXAMINER

MAYES, LAURIE A

ART UNIT PAPER NUMBER

1653

DATE MAILED: 08/04/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/074,389

Applicant(s)

SCIALDONE ET AL

Examiner

Laurie Mayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 20 May 2003.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1 and 4-23 is/are rejected.
- 7) ☒ Claim(s) 2, 3 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The applicant's response of May 13, 2003 has been entered. In view of the amendments, the rejections under 35 U.S.C. 112 are withdrawn.

Claim Objections- 35 CFR 1.75(c)

In view of the amendment, the rejection of claims 5 and 6 under 35 CFR 1.175(c) is withdrawn. The rejection of claim 4 under 35 CFR 1.175(c) is maintained as claim 4 could still include a tripeptide which is capped by more amino acids or by another peptide. Therefore, claim 4 fails to claim subject matter that narrows the scope of claim 1 but rather enlarges the scope of claim 1.

Allowable Subject Matter

Claims 2 and 3 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claims 1, 4 and 7 rejected under 35 U.S.C. 102(a) as being anticipated by Brown et al. (Annals of Surgical Oncology V7, N10 (Dec.), p743-749 (2000)). Brown et al. teach anti-angiogenic tripeptides of the formulas RGD and NGR (p. 744, col. 1, 3rd para. and Fig. 1).

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Brown et al. teach all of the elements of claims 1, 4 and 7 and these claims are anticipated under 35 U.S.C. 102(a).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 4-17 and 20-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blaschuk et al. (US 6,031,072). Blaschuk et al. teach a small peptide of four or more amino acids comprising the sequence XHAV, wherein X may be any amino acid (col. 3, lines 14-17), that inhibits angiogenesis in a mammal (col. 2, lines 66-67 to col. 3, lines 1-10 and col. 3, lines 60-64) (present claims 1 and 23) and wherein the peptide may be capped by an acetyl group and a C-terminal amide group (col. 3, lines 20-30) (present claims 5, 6), linked in a composition to a drug (see claim 21) (present claim 7, 8) and administered to an inflamed tissue of a tumor to inhibit angiogenesis (col. 4, lines 5-10 and for inflamed tissue see col. 20, lines 10-30) (present claims 9, 12, 13), administered to a mammal to inhibit angiogenesis (col. 3, lines 60-64) (present claims 10, 11), or administered to treat rheumatoid arthritis (col. 28, lines 20-23) (present claim 14) via a pharmaceutically acceptable medium, namely, a skin patch (col. 5, lines 1-2) (present claims 15, 20) or via biodegradable polymers (col. 17, lines 1-10) (present claim 17) and in combination with an antibiotic (col. 18, lines 40-62) (present claim 21) and in surgery or

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chemotherapy (col. 20, lines 10-30) (present claim 22). Blaschuk et al. do not teach a tripeptide. Given that Blaschuk et al. teach that the tripeptide HAV within a larger peptide is responsible for the antiangiogenic properties of the peptide, it would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to administer the tripeptide alone to treat angiogenesis and to administer it via any well-known delivery method such as skin patches, osmotic pumps, orally, or nasally, for example (present claim 16).

Claims 1, 9, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blaschuk et al. as applied to claims 1 and 9 above, and further in view of Windham et al. (Journal of Virology, Vol. 71, No. 11, Nov. 1997, pp. 8221-8229). Wickham et al. teach a method of incorporation of an angiogenesis-inhibitory tripeptide sequence into an adenovirus (p. 8221, col. 1, 1st paragraph) and nucleic acids (p. 8222, col. 2, last para.). As recombinantly produced proteins carry the advantage of being more pure and often cheaper than purified proteins, it would have been obvious to one of ordinary skill in the art at the time of the invention by the applicant to administer the angiogenesis-inhibitory peptide to tissue via encoding nucleic acid and incorporation into a vector, adenovirus or DNA. Thus, the claimed invention was prima facie obvious to make and use at the time the claimed invention was made.

In view of the applicant's arguments regarding the 102(a) rejection of claims 2 and 3 over Maeshima et al., the 102(a) rejection is withdrawn.

Conclusion

Claims 1 and 4-23 are rejected and claims 2 and 3 are objected to.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laurie Mayes whose telephone number is (703) 605-1208. The examiner can normally be reached on Monday through Friday from 9 Am to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1123.

L. Mayes
Laurie Mayes
Patent Examiner
Art Unit 1653
July 31, 2003

Christopher S. Low
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